

August 11, 2000

Jane E. Henney, MD  
Commissioner  
Food and Drug Administration  
Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20855

Re: Public Workshop on CLIA Waiver Criteria

Dear Dr. Henney:

The national medical organizations listed below are strongly opposed to a more restrictive interpretation of those laboratory tests that qualify for a certificate of waiver under the Clinical Laboratory Improvements Act (CLIA) of 1988. The questions raised in anticipation of the August 14-15 Food and Drug Administration (FDA) Public Workshop on the CLIA Waiver Criteria suggest that CLIA rules for certificate of waiver may be further tightened. If so, this likely would force even more physicians to stop performing the simple laboratory testing they have been safely and efficiently performing for the last five years.

The seventy five thousand physician office laboratories that confine their laboratory testing to the waived and microscopy categories provide an important and essential service to their patients. Through the use of waived laboratory testing physicians are able to quickly and safely perform these simple tests with immediate results that improve the quality of care. Physicians are thus able to initiate immediate medical treatment and begin appropriate medications. Accordingly, we strongly urge the FDA to retain the current definition of waiver.

Sincerely,

American Academy of Dermatology  
American Academy of Family Physicians  
American Academy of Neurology  
American Academy of Pediatrics  
American College of Cardiology  
American College of Obstetricians and Gynecologists  
American College of Occupational and Environmental Medicine  
American College of Physicians-American Society of Internal Medicine  
American College of Rheumatology  
American Medical Association  
American Medical Group Association  
American Society for Gastrointestinal Endoscopy  
American Urological Association  
Joint Council of Allergy Asthma and Immunology  
Medical Group Management Association  
Renal Physicians Association

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